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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,291	03/25/2004	Cynthia C. Bamdad	M1015.70002US01	6035
7590	10/04/2005		EXAMINER	
Timothy J. Oyer, Ph.D. Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 10/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/809,291	BAMDAD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 September 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,9,21,34,39 and 205-216 is/are pending in the application.
- 4a) Of the above claim(s) 206-208,210-214 and 216 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,9,21,34,39205,209,215 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, Claims 1-3, 9, 21, 34, 39, 205, 209 and 215 in the reply filed on 09/21/05 is acknowledged. The traversal is on the ground(s) that the methods comprising the colloid particles, the composition comprising a colloid particle, and the article comprising the colloid particle are closely related each other as product and process of use or as components of each other and that there is not an undue burden placed upon the Examiner to search and consider all of the closely related claims.. This is not found persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. Further, while searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 211 and 216 are withdrawn from further consideration as being directed to a non-elected invention. Further, claims 206-208, 210, 212-214 are withdrawn from further consideration because the Examiner was unable to determine the grouping of claims 206-208, 210, and 212-214 (see election restriction filed 08/23/05).

***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 9, 21, 34, 39, 205, 209 and 215 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the body of the claim lacks a preamble and it is unclear what the method is directed to.

Claim 1, line 2 the recitations "allowing" and "the ability" is vague and indefinite. The recitations appear to be mental steps and no actual step is provided which shows how the colloidal particle is given the ability to become immobilized.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of contacting the colloidal particle with the non-colloidal structure.

Claim 1, line 4 the recitation "relative to" is vague and indefinite. The term "relative to" is a relative term which renders the claim indefinite. The term "relative to" is

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not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does the colloid particle bind to the non-colloidal structure or are the colloid particle and the non-colloidal structure in close proximity to each other?

Claim 2 the recitation "auxiliary" is vague and indefinite. It is unclear if this is the only signal generated or is there another signal. Further, it is unclear what purpose the auxiliary signaling entity provides in the method. Is the signal detected to determine immobilization of the colloidal and non-colloidal structures or does the signal serve another purpose in the method?

Claim 21 "the target" there is insufficient antecedent basis for this limitation.

Claim 21 is vague and indefinite because it is unclear what relationship exists between the ligand the target, the colloidal particle and the non-colloidal particle and the candidate drug. It is unclear what steps are occurring in this method and also what the method is.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ching et al (EP 0299428).

Ching et al disclose a method comprising a colloidal particle labeled first specific binding reagent which is transported to a first zone where a second reagent has been immobilized to chromatographic substrate material (non-colloidal structure). Ching et al disclose that the labeled first reagent and the analyte if present are immobilized by reaction with the second reagent (p. 9, lines 18-32) and a visibly detectable signal is produced. Ching et al disclose that the specific binding reagents are members of a specific binding pair consisting of a ligand and a receptor. Ching et al disclose that the reagents can be antibodies and analytes, avidin and biotin, streptavidin and antibiotin (p. 18, lines 27-37).

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al (US 4,853,335).

Olsen et al disclose a method for detecting an antigen in a biological specimen. Olsen et al disclose a colloidal gold labeled ligand or antiligand reagent or antiligand bound solid phase particles which are combined with a sample. Olsen et al disclose

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that the particles are captured on a membrane (non-colloidal structure) and visually inspected for color (col 2, line 67 – col 3 line 15).

8. Claims 1, 9 and 205 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al (US 5,589,401).

Hansen et al disclose a method for the simultaneous determination of one or more analytes in a fluid. Hansen et al disclose polymeric microspheres (non-colloidal structure) coated with a first binding molecule, colloid particles coated with a second binding molecule, and an analyte that is complementary to both binding molecules. In the presence of the analyte a complex is formed and the colloid particle is immobilized relative to the polymeric microsphere (col 3, lines 59-64). Hansen et al disclose that the polymeric microsphere is a polystyrene microsphere (col 7, lines 18-19). Hansen et al disclose the use of a plurality of microspheres and reagents which allow for the determination of a plurality of analytes (col 9, line 64 – col 10, line 22). Hansen et al disclose that one can analyze concurrently multiple analytes by using the appropriate reagents (col 9, line 64 – col 10, line 22)

9. Claims 1-3, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Sigal et al (US 6,319,670).

Sigal et al disclose a method comprising colloidal particles having one or more assay ligands immobilized on its outer surface. Sigal et al also disclose that the colloidal particles have plurality of electrochemiluminescent moieties (auxiliary signaling entity) immobilized on the particle. Sigal et al disclose assays for an analyte of interest comprising forming a composition of the sample and one or more colloidal particles,

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incubating the composition to form a complex and causing the complex to bind to an assay-ligand immobilized on an electrode (non-colloidal structure) and determining the presence of the reactants (col 2, line 47 – col 3, line 5). Sigal et al disclose that the assay-ligands include proteins (oligopeptides, polypeptides) and nucleic acids (col 3, lines 32-56).

10. Claims 1, 9 and 215 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen et al (US Patent 6,342,349).

Virtanen et al disclose an immunoassay method comprising colloid particles (col 37, lines 40-42), which are immobilized to a substrate (non-colloidal structure). Virtanen et al disclose that the colloid particle and the substrate (non-colloidal structure) are exposed to cleavable spacer molecules (entity), which comprise cleavage sites. (see figures 1 and 3). Virtanen et al disclose that the cleavable spacer molecules bind to both the colloid particle and to the non-colloidal structure. Virtanen et al disclose that enzymes can be used as cleavage reagents by incorporating into the spacer a moiety that serves as the substrate (enzyme substrate) for the given enzyme (col 34, lines 15-17). Virtanen et al disclose that the analyte can be a drug candidate (col 55, line 53 – col 56, line 67). Virtanen et al disclose that the cleavable spacer molecules also comprise antibodies specific for the analyte of interest. Virtanen et al disclose that when the analyte (drug candidate) is present it binds to the antibody and prevents the chemical cleaving agent (enzyme) from cleaving the colloid particle from the surface (col 18, lines 1-16). Virtanen et al disclose that the presence and absence of the colloid particle may then be detected.

11. Claims 1-3, 205 and 209 rejected under 35 U.S.C. 102(e) as being anticipated by Bambad et al (US 6,541,617).

Bamdad et al disclose a method for detecting a complex in which a transfer particle (non-colloidal structure) with a binding ligand which binds to a target analyte. Bamdad et al disclose that this transfer particle can be a magnetic particle (col 4, lines 34-35). Bamdad et al disclose that a reporter particle (colloidal particle) with a binding ligand. Bamdad et al disclose that the reporter particle also binds to the analyte to form a complex of transfer particle, analyte and reporter particle (col 2, lines 39-67 and Figure 1A). Bamdad et al disclose that the reporter particle can comprise a self-assembled monolayer and electron transfer moieties (signal entities).

12. Claims 1 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Oberhardt (US 6,251,615).

Oberhardt discloses a method comprising an immobilized cell (non-colloidal structure and contacting the cell with a fluorescent particle (colloidal particle) which comprises a ligand to bind to the immobilized cell (col 17 and Fig 7C) and detecting the complex.

#### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et

al (EP 0299428) in view of Charych et al (US 6,001,556).

See above for the teachings of Ching et al.

Ching et al differ from the instant invention in failing to teach allowing the colloidal particle the ability to fasten to the non-colloidal structure in the presence of a candidate drug for interruption of the binding of the ligand.

Charych et al disclose a competitive assay in which a drug candidate is introduced into a system containing a receptor and its reciprocal binding partner.

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Charych et al disclose that if the drug binds to the receptor or modifies the binding partner's binding capacity, there is a decrease in the signal (col 20, lines 1-40).

Charych et al disclose that this provides for the development and improvement of drugs by observing competitive inhibition of natural binding events between all surfaces or binding sites and their natural bioactive ligand.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate candidate drugs and their reagents as taught by Charych et al into the method of Ching et al because Charych et al shows that that this provides for the development and improvement of drugs by observing competitive inhibition of natural binding events between all surfaces or binding sites and their natural bioactive ligand.

17. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al (US 6,319,670) in view of Altieri et al (US 6,346,389).

See above for teachings of Sigal et al.

Sigal et al differ from the instant invention in failing to teach the binding partner is adapted for linkage to the particle by glutathione/glutathione-s-transferase ligand interaction.

Altieri et al disclose glutathione-s-transferase fusion proteins which are immobilized onto a glutathione substrate. Altieri et al disclose that this immobilization allows for the separation of protein-protein complexes from uncomplexed forms, as well as to accommodate automation of an assay (col 10, lines 9-36).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate glutathione-s-transferase fusion proteins and glutathione substrates as taught by Altieri et al into the method of Sigal et al because Altieri et al disclose that this immobilization allows for the separation of protein-protein complexes from uncomplexed forms, as well as to accommodate automation of an assay.

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rohr (5,445,970) disclose magnetic beads which comprise a ligand and form a complex with analyte and immobilized beads which are within another phase (col 7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
September 27, 2005



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
09/29/05